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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,563	10/23/2001	Mary Theresa Murray	3087.00007	7737

7590 02/22/2006

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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,563	MURRAY ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,7,8,21-24 and 43-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,7,8,21-24 and 43* is/are rejected.

7)☒ Claim(s) *45* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 11/28/2005.

The amendment filed 11/28/2005 is acknowledged and has been entered. Claims 1, 2, 4, 7, 8, 21-24 and 43-45 are currently pending in the application and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is indefinite because it depends on a cancelled claim. Specifically, claim 24 depends on cancelled claim 27, thus rendering claim 24 indefinite.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 7, 8, and 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

In this case, the claims encompass a eukaryotic translation initiator and/or an activator of a eukaryotic translation initiator mRNA. Looking to the specification for guidance on the scope of the term "eukaryotic translation initiator", the specification clearly indicates "A translation initiation factor is a product that initiates or begins protein synthesis. The translation initiation factor can be the factor specifically disclosed herein, namely, elF4E, or it can be any chemical that is capable of initiating protein synthesis." (See page 10; Emphasis added). Furthermore, the specification does not set forth a specific definition for "eukaryotic translation initiator". Therefore, in view of the disclosure that a "translation initiation factor" can be "any chemical that is capable of initiating protein synthesis" and in the absence of any specific definition for "eukaryotic translation initiator", the phrase "eukaryotic translation initiator" is interpreted as encompassing any chemical that is capable of initiating eukaryotic protein synthesis. As such,

the claims encompass a genus of "eukaryotic translation initiators" that includes chemicals that are not structurally related. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). In this case, the skilled artisan cannot envision the detailed chemical structure of the "eukaryotic translation initiator" chemicals encompassed by the claims, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Additionally, claims 1, 2, 4, 7, 8, 43 and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not provide an enabling disclosure for the full scope of the claims for the reasons of record set forth in the 5/17/2005 Office Action.

Specifically, claims 1, 2, 4, 7, 8, 43 and 44 are enabled for:

A method for augmenting transient protein synthesis in a cell *in vitro* by administering mRNA encoding eIF4e directly to the cell, wherein administering said mRNA to said cell transiently increases protein synthesis in said cells; and

A non-therapeutic method for augmenting transient protein synthesis in a cell *in vivo* by administering mRNA encoding eIF4e directly to the cell, wherein administering said mRNA to said cell transiently increases protein synthesis in said cells;

but are not enabled for therapeutic treatment of cells in vivo.

It is noted that this is not an acknowledgment that the specification has proper support for the above indicated embodiments. Applicants are respectfully reminded that they should provide the specific location (by page and line number) where support for any claim amendment can be found in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Qui et al. (Gene Therapy, 1996, cited by Applicants in IDS received 7/1/04) for the reasons set forth in the 5/17/2005 Office Action.

Response to Arguments

Applicant's arguments filed 11/28/2005 have been fully considered.

With respect to the rejection of claims under 35 USC 112, 2nd paragraph, the amendment to claims 21-24 renders the rejection moot.

With respect to the rejection of claims under 35 USC 112, 1st paragraph (New Matter), the amendment to claims 21, 23, 24 renders the rejection moot.

With respect to the rejection of claims 1, 2, 4, 7, 8, 43 and 44 under 35 USC 112, 1st paragraph (enablement), Applicants assert that the instant claims are not explicitly drawn to methods of augmenting wound healing. Furthermore Applicants point out that claim 5 (which specifically indicated the claims encompassed wound healing) has been cancelled. Therefore, Applicants assert that it is improper to read claims 1, 2 and 4 as encompassing wound healing. Applicants indicate that the invention can be used for either (a) harvesting increased levels of cellular proteins (as in claims 1, 2, 4) or (b) increasing collagen synthesis and tensil strength in wounds (as in claims 21-24). Applicants then assert that the instant claims are not related to wound healing (see page 6, last paragraph of the 11/28/05 response).

This is not persuasive because claims are given their broadest reasonable interpretation consistent with the specification. In the instant case, it is respectfully pointed out that the claims are not explicitly limited to non-therapeutic methods (such as in vitro methods). Furthermore, as acknowledge in Applicants response (as indicated above) the invention can be used for increasing collagen synthesis and tensil strength in wounds (i.e., wound healing). Furthermore, it

is respectfully pointed out that the specification appears to disclose that the preferred embodiment (if not the only disclosed use) of the instant invention is for wound healing. As such, and in the absence of any specific limitations indicating that the claims are not drawn to wound healing, and given the broadest reasonable interpretation consistent with the specification, claims 1, 2, 4, 7, 8, 43 and 44 do, in fact, encompass methods for treating wounds. Therefore Applicants arguments are not persuasive with respect to the instant claims.

With respect to the rejection of claims 1, 2, and 4 under 35 USC 102(b), Applicants argue that anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference and in the instant case that Qui does not teach that the growth hormone used in the experiments have are the same structure as the claimed translation initiation factors. Furthermore, Applicants argue that Qui does not teach delivering growth hormone mRNA to cells in vivo, on in vitro.

In response, it is respectfully pointed out that the instant claims do not explicitly recite that the method is limited to cell *in vivo.* As such, given their broadest reasonable interpretation, the claims encompass both *in vivo* and *in vitro* embodiments. Therefore, it is irrelevant if Qui teaches administering the growth hormone mRNA in vivo because it does teach administering the growth hormone mRNA to cells in vitro, which is encompassed by the claims. With respect to Applicants arguments that the growth hormone mRNA taught by Qui is not the same structure as the claimed eukaryotic translation initiator, it is respectfully pointed out that the instant claims do not set forth any particular structure for the claimed eukaryotic translation initiators encompassed by the claims. Furthermore, looking to the specification for guidance on scope of

the term "eukaryotic translation initiator", the specification clearly indicates, "A translation initiation factor is a product that initiates or begins protein synthesis. The translation initiation factor can be the factor specifically disclosed herein, namely, elF4E, or it can be any chemical that is capable of initiating protein synthesis." (See page 10; Emphasis added). Furthermore, the specification does not set forth a specific definition for "eukaryotic translation initiator". Therefore, in view of the disclosure that a "translation initiation factor" can be "any chemical that is capable of initiating protein synthesis" and in the absence of any specific definition for "eukaryotic translation initiator", the phrase "eukaryotic translation initiator" is interpreted as encompassing any chemical that is initiating eukaryotic protein synthesis. As such, the claims encompass a genus of "eukaryotic translation initiators" that includes any chemical that is capable of initiating protein synthesis. As was previously indicated human growth hormone would clearly be recognized by one of skill in the art as a chemical that stimulates cell growth, which would necessarily include the initiation of protein synthesis in the growing cells. Also see Steenos (1994, previously cited) which teaches, "Growth hormone has an anabolic action in the stimulation of protein synthesis and also effects the metabolism of carbohydrates, lipids, minerals and fluids... " (See p. 100). Therefore, the human growth hormone taught by Qui is a eukaryotic translation initiator, given the broad definition of translation initiator disclosed in the specification. Therefore, Applicants arguments are not persuasive.

Claim Objections

Claim 45 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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